IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES LLC and EDWARDS LIFESCIENCES PVT, Inc.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 12-23 (GMS)
	)	REDACTED - PUBLIC VERSION
MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L., MEDTRONIC VASCULAR GALWAY LTD., MEDTRONIC, INC., and MEDTRONIC VASCULAR, INC.,	)	
Defendants.	)	

EDWARDS' LETTER TO THE HONORABLE CHIEF JUDGE GREGORY M. SLEET FROM JACK B. BLUMENFELD IN OPPOSITION TO MEDTRONIC'S MOTION *IN LIMINE* CONCERNING ITS EVIDENTIARY ISSUE NO. 5 AND IN SUPPORT OF EDWARDS' MOTIONS *IN LIMINE* CONCERNING ITS EVIDENTIARY ISSUES NOS. 4 AND 5

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REDACTED - PUBLIC VERSION

The Honorable Gregory M. Sleet
United States District Court
for the District of Delaware
844 North King Street
Wilmington, Delaware 19801

VIA ELECTRONIC FILING

Re: *Edwards Lifesciences LLC, et al.* v. *Medtronic CoreValve LLC, et al.*, C. A. No. 12-023 (GMS)

Dear Chief Judge Sleet:

Pursuant to the Court's December 5, 2013 Order (D.I. 130 at 5; D.I. 131 at 47), Edwards respectfully submits this letter brief in opposition to Medtronic's Evidentiary Issue No. 5 (MDT Ltr. Br., D.I. 134; D.I. 126-1, Ex. W, at 2) and in support of Edwards' Evidentiary Issue Nos. 4 and 5, all of which relate to Edwards' infringement claims under 35 U.S.C. § 271(f). Medtronic seeks to preclude Edwards from presenting evidence that [redacted] (*See* D.I. 126-1, Ex. V, at 2).[1]

I. [redacted]

[redacted]

[1] Relevant here are the meaning of "supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention" as set forth in § 271(f)(1), and the meaning of "supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use" as set forth in § 271(f)(2).

[redacted]

[redacted]

[redacted]

[redacted] Medtronic's entire argument is based on a flawed interpretation of *Microsoft Corp.* v. *AT&T Corp.*, 550 U.S. 437 (2007). Tellingly, Medtronic ignores the only salient point from *Microsoft* relevant to its evidentiary issue here: the definition of "component" under § 271(f) as "a constituent part," "element," or "ingredient."[2] *Id.* at 449 n.11.

[redacted]

Microsoft hinges on two inquiries unrelated to the instant matter: (i) "when, or in what form, does software qualify as a 'component' under § 271(f)"; and (ii) were "components" of the foreign-made computers "supplied" by Microsoft "from the United States." *Microsoft*, 550 U.S. at 447. Microsoft stipulated to infringement when Windows software is loaded onto a computer in the United States. *Id.* at 446. At issue was Microsoft's supply from the United States to foreign manufacturers of master disks with Windows software. *Id.* at 445-46. The foreign

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[2] The Federal Circuit later adopted this same meaning of "component" in *Cardiac Pacemakers, Inc.* v. *St. Jude Medical, Inc.*, 576 F.3d 1348, 1363 (Fed. Cir. 2009).

[3] Claim 1 of the '825 Patent claims "a flexible valvular structure made with pericardial tissue" and "an internal cover made with pericardial tissue." '825 Patent Claim 1, col. 21, ll. 49, 55) (emphasis supplied).

manufacturer would use the master disk to generate copies, and it was those new copies made abroad, not the master disk supplied from the U.S., that were then installed on the foreign manufacturer's computers. *Id.*

To resolve the first inquiry, the *Microsoft* Court analogized software in the abstract to a blueprint and set forth that "[a] blueprint may contain precise instructions for the construction and combination of the components of a patented device, but it is not itself a combinable component of that device." *Id.* at 450. Thus, only "a copy of Windows, not Windows in the abstract, qualifies as a 'component' under § 271(f)." *Id.* at 451-52. On the second inquiry, the Court held that "the very components supplied from the United States, and not copies thereof, trigger § 271(f) liability when combined abroad to form the patent invention at issue. . . . [T]he copies of Windows actually installed on the foreign computers were not themselves supplied from the United States. . . . Without stretching § 271(f) beyond the text Congress composed, a copy made entirely abroad does not fit the description 'supplie[d] . . . from the United States.'" *Id.* at 453-54.

The facts of *Microsoft* are inapposite. [redacted] In *Lucent Technologies Inc.* v. *Gateway, Inc.*, 580 F.3d 1301 (Fed. Cir. 2009), the Federal Circuit, analyzing a contributory infringement claim under 35 U.S.C. § 271(c),[5] noted that an infringer "'should not be permitted to escape liability as a contributory infringer merely by embedding [the infringing apparatus] in a larger product with some additional, separable feature . . . .'" *Id.* at 1320 (quoting *Ricoh Co.* v. *Quanta Computer Inc.*, 550 F.3d 1325, 1337 (Fed. Cir. 2008), *cert. denied*, 577 U.S. 936 (2009)). [redacted]

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[4] Medtronic misreads *Microsoft's* reference to an "extra step" to mean that if an extra processing step is required abroad, it cannot be a "component" of the claimed invention. *Microsoft*, 550 U.S. at 451. The "extra step" in *Microsoft* was the "extra step" required to make "intangible, uncombinable information" (*i.e.*, a non-component) into a "usable, combinable part" (i.e., a component). [redacted]

[5] 35 U.S.C. § 271(c) (contributory infringement) has identical language to 35 U.S.C. § 271(f)(2) concerning a "staple article" and "substantial non-infringing uses." Therefore, cases interpreting this language are applicable to both § 271(c) and § 271(f)(2). (*See* 5 Donald S. Chisum, CHISUM ON PATENTS § 17.03[1] (2012)).

[redacted]

II. [redacted]

[redacted]

[redacted]

[redacted] Each is improper.

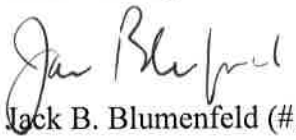
The law is clear: noninfringing uses under § 271(f)(2) must be *actual* uses that employ treated pericardial tissue that is the same as the pericardial tissue *actually supplied* by Medtronic. *See, e.g.*, *Hodosh* v. *Block Drug Co.*, 833 F.2d 1575, 1578 (Fed. Cir. 1987) (holding that "the material *actually sold*" must be a "staple article") (emphasis added); *Golden Blount, Inc.* v. *Robert H. Peterson Co.*, 438 F.3d 1354, 1364 (Fed. Cir. 2006) (requiring "evidence that anyone *actually made or used* the assembly" in a non-infringing manner) (emphasis added); *Mentor H/S Inc.* v. *Medical Device Alliance, Inc.*, 244 F.3d 1365, 1372 (Fed. Cir. 2001) (lack of evidence of actual noninfringing use entitled jury to find contributory infringement); *see also Vita-Mix Corp.* v. *Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009) ("non-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental."). Thus, Medtronic's attempt to introduce evidence of (i) [redacted]

[redacted]

III. Conclusion

Edwards respectfully requests that the Court deny Medtronic's Evidentiary Motion No. 5 and grant Edwards' Evidentiary Motion Nos. 4 and 5.

Respectfully,



Jack B. Blumenfeld (#1014)

JBB/dlw
Enclosures
cc: Clerk of the Court (Via Hand Delivery; w/ encl.)
All Counsel of Record (Via Electronic Filing; w/ encl.)

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES LLC AND EDWARDS LIFESCIENCES PVT, INC., Plaintiffs, v. MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L., MEDTRONIC VASCULAR GALWAY LTD., MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC., Defendants.	C.A. No.: 12-23 (GMS)

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

VIDEOTAPED DEPOSITION OF DAVID A. MONTECALVO

January 18, 2013

The videotaped deposition of DAVID MONTECALVO, a witness produced and sworn before me, Lisa A. Blanks, RPR, CRR, was taken on behalf of the Plaintiffs at the offices of Robins, Kaplan, Miller & Ciresi L.L.P., 800 LaSalle Avenue, 7th Floor, Minneapolis, MN, on the 18th day of January, 2013, at 9:09 a.m.

Galway?

A. For this particular option that was considered, yes.

Q. Okay. When you look at the line that says, "Santa Ana," it says, "Tissue processing 100 percent."

Do you see that?

A. Yes.

Q. What is tissue processing referring to?

A. The incoming inspection of the tissue and then the subsequent tissue fixation process.

Q. Just to step back a moment. When we're referring to the Medtronic CoreValve product as pictured, for example, in Exhibits 248 and 249, what material components is the device made of?

MS. ROBERG-PEREZ: Objection, form.

MR. EGAN: You can answer.

THE WITNESS: There are pericardial tissue components. There is a nitinol frame, and there is suture material that's used in the manufacturing of the device.

Q. BY MR. EGAN: So effectively, it's pericardial tissue, a nitinol frame and sutures, is that correct?

A. That's correct.

Q. And so when we look at Exhibit 251 and it talks about tissue processing in Santa Ana, that's

A. Correct.

Q. And I believe you testified earlier that the valve material in the Melody valve is a bovine jugular valve material, correct?

A. Correct.

Q. So other than the Medtronic CoreValve device that's being assembled in the Tijuana facility, are there any other devices in the Medtronic Tijuana facility that used porcine pericardium?

A. No.

Q. So the Medtronic CoreValve device is the only device in the Tijuana facility that uses porcine pericardium?

A. That is correct.

Q. I'm next going to hand you what we're going to mark as Exhibit 252.

(Montecalvo Exhibit 252 was marked for identification.)

Q. BY MR. EGAN: For the record, Exhibit 252 bears Bates numbers Medcore 974827 to Medcore 974846.

Do you recognize this document, Mr. Montecalvo?

A. Yes.

Q. And what is this document?

A. This is a quarterly update relative to the

Q. BY MR. EGAN: Are you familiar with the AOA process?

A. Generally familiar, yes.

Q. And what is the AOA process?

A. It's a process we use to treat our tissue to minimize or eliminate the amount of calcification that occurs on the tissue.

Q. Do you know at what step of the manufacturing procedure the AOA treatment is applied?

A. I do not know specifically.

Q. Do you know if Medtronic is currently treating Medtronic CoreValve devices with the AOA treatment in both Medtronic Mexico and in Mexico Irvine?

A. Yes, we are.

Q. So both sites are using the AOA treatment process?

A. I believe so, yes.

Q. Going back to Medtronic's exportations of porcine pericardial material, does Medtronic export porcine pericardial tissue from Irvine to Mexico intending that it'll be combined to form the Medtronic CoreValve product?

A. Yes.

Q. And that's true for each of porcine pericardial -- excuse me, that's true for each of

porcine pericardium coupons, pericardial sacs and laser cut leaflets and skirts?

A. Yes.

MR. EGAN: Thank you very much for your time. I have no further questions.

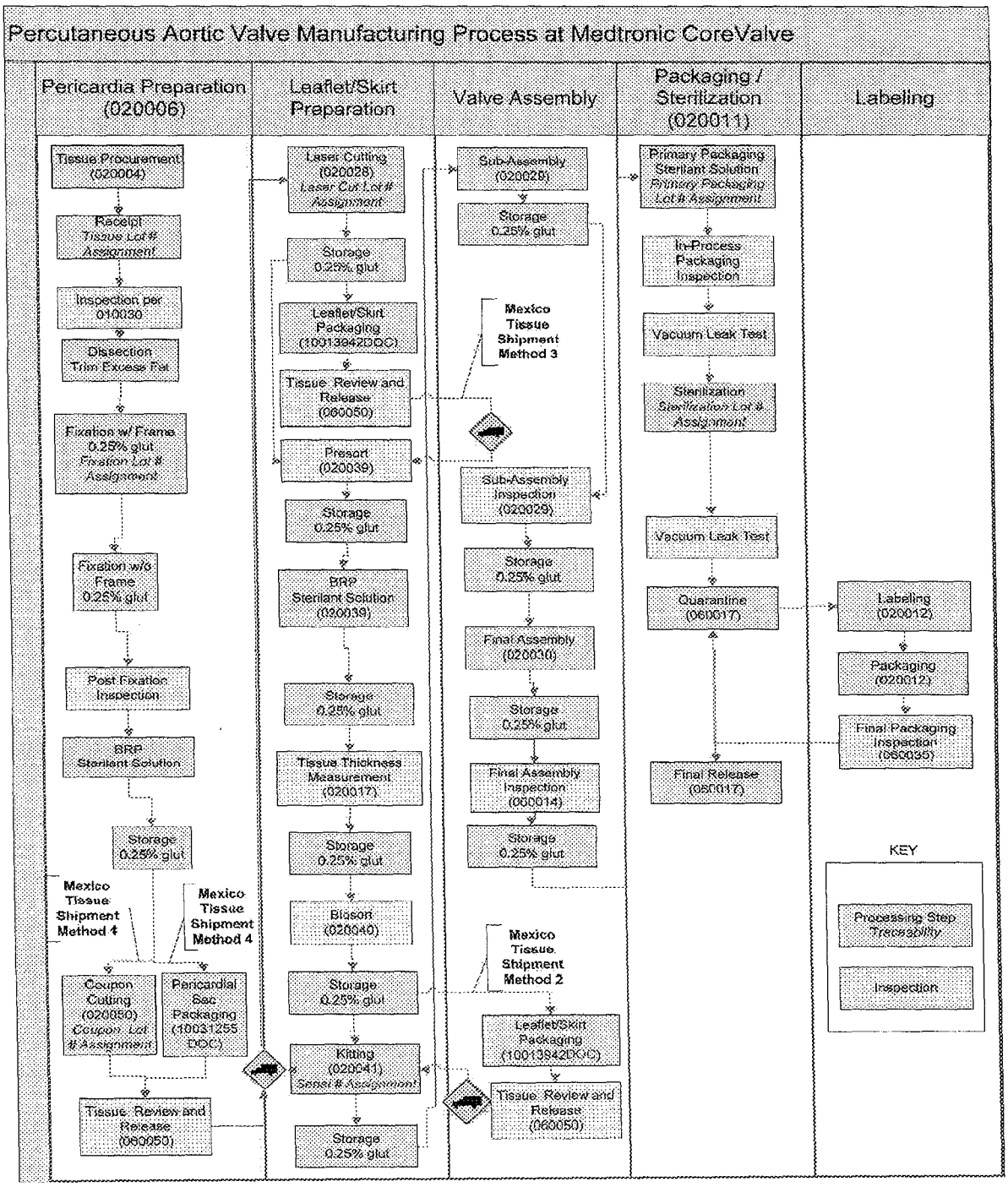
Given that it's the final day of discovery, I would like to leave open the issue with regards to the Excel spreadsheet and also reserve Edwards' rights to supplement any discovery responses citing to testimony from today, should it be relevant.

MS. ROBERG-PEREZ: Okay.

THE VIDEOGRAPHER: We're off the record at 5:23 p.m.

(Concluded at approximately 5:23 p.m.)

EXHIBIT B



BRP – Bioburden Reduction Process

Figure 1: Percutaneous Aortic Valve Manufacturing Flowchart

EXHIBIT C

Medtronic	Biological Test Plan for Low-Density Polyethylene (LDPE) Bags	10014325DOC Rev. 1A

Biological Test Plan for Low-Density Polyethylene (LDPE) Bags

1.0 PURPOSE

To characterize and evaluate LDPE bags supplied by Uline® and McMaster-Carr® for biological safety and biocompatibility.

2.0 SCOPE

This test plan applies to Uline® 20" x 24" LDPE bags, supplier model # S-1454, and McMaster-Carr® 20" x 24" LDPE bags, supplier model # 1928T99.

3.0 INTRODUCTION

The CoreValve percutaneous aortic valve (PAV) is a three component device composed of: porcine pericardium, a Nitinol frame, and a polytetrafluoroethylene (PTFE) suture. Currently, porcine pericardium received at the design and manufacturing site in Irvine is packaged and shipped in glass jars (0100229) with a lid (1100337-063) and gasket (1100442-063) to the secondary manufacturing facility in Tijuana. Two brands of open-top bags composed of 100% LDPE film are being evaluated as transport vessels to replace the glass shipping jars. These tissues will be shipped in a 0.25% glutaraldehyde solution (030001) for a maximum of seven days over a temperature range of 0°- 40°C (32° - 104°F). The LDPE bag will serve as a conduit between steps in the manufacturing process; it is not represented in the final medical device and does not have any direct contact with the patient. However, since this vessel will transport components that are intended for long-term implantation, a biological evaluation will be performed to support patient safety.

4.0 MATERIAL AND TISSUE CONTACT

LDPE bags from both suppliers have similar properties. The rationale for using two suppliers is to ensure Medtronic business continuity in the event of a break in the supply chain from one of the two companies. A brief description of these devices follows:

Table 4.1

Material	Component	Supplier model #	Characterization of Tissue Contact (ISO 10993-1)
100% virgin LDPE film (Uline®)	Open-top Shipping bag	S – 1454	NONE
100% virgin LDPE film (McMaster-Carr®)	Open-top Shipping bag	1928T99	NONE

4.1 The LDPE bag is not intended to have any patient tissue or blood contact. This classifies it as a non-tissue contacting component by the ISO 10993-1 definition. The bag will contain CoreValve porcine pericardium suspended in 0.25% glutaraldehyde solution during a shipping phase of the manufacturing process. The pericardium being

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES, LLC, and
EDWARDS LIFESCIENCES PVT, INC.,

Plaintiffs,

-vs-

Civil Action No.
12-23-GMS

MEDTRONIC COREVALVE, LLC,
MEDTRONIC CV LUXEMBOURG S.A.R.I,
MEDTRONIC VASCULAR GALWAY, LTD.,
MEDTRONIC, INC., and MEDTRONIC VASCULAR, INC.,

Defendants.

VIDEOTAPED DEPOSITION

OF

GARY L. LOOMIS, Ph.D.

*** HIGHLY CONFIDENTIAL ***

ATTORNEYS' EYES ONLY

DATE TAKEN: 4/15/13 BY: Amy L. Larson, RPR

that is used to make the CoreValve PAV?

MS. OBERTS: Objection to form.

THE WITNESS: No, I think I've already answered it. It's -- it's a -- ingredient is -- I'm not making a recipe here. It's -- it's a starting -- it's a starting material. It's one of the materials -- no, it's one of the materials used to -- to make it. If they were going to make it out of a -- out of a plastic material, polyurethane, and somebody shipped them sheets of polyurethane to cut the mold of, it would be the same thing, they're just shipping them the material. But their sheets of polyurethane have other uses and the sheets of porcine pericardium have other uses.

BY MR. EGAN:

Q. In your opinion, correct?

A. No, with my knowledge. I know that Vascutek used to make -- used to make vascular patches, at least they did, maybe they still do, out of -- out of porcine pericardium, they used to get sheets of it.

Q. Well, there's a dispute between you and

Dr. Buller, is there not, as to whether or not they're the same pericardial tissue due to the amount of Glutaraldehyde that's used to treat those pieces of pericardium?

MS. OBERTS: Objection. I'm not sure there was a question there.

THE WITNESS: Yeah, I would -- just make it into a question. I agree. I'd like to hear a more succinct question.

MR. EGAN: Sure.

BY MR. EGAN:

Q. You understand that Dr. Buller has opined that the pericardial patches made by Vascutek are not noninfringing alternatives because they are treated with a different concentration of Glutaraldehyde than what Medtronic uses with its pericardial coupons?

MS. OBERTS: Objection to form. I'm still not sure there's --

THE WITNESS: Yeah, so when you say --

MS. OBERTS: -- a question there.

THE WITNESS: When you say noninfringing alternatives, we're speaking with -- with -- we're speaking with respect

to the 271(f) is that --

BY MR. EGAN:

Q. You -- you've reviewed Dr. --

THE WITNESS: -- that term that you used.

BY MR. EGAN:

Q. You've reviewed Dr. Buller's opinion, correct?

A. Yes.

Q. Okay. And Dr. Buller has opined that the Vascutek pericardial patches are different from the pericardial coupons and pericardial sacks that are used by Medtronic --

MS. OBERTS: Objection.

BY MR. EGAN:

Q. -- is that correct?

MS. OBERTS: Objection to form. I'm still not sure if there's really a question --

THE WITNESS: Different in shape?

MS. OBERTS: -- or a statement.

THE WITNESS: They're certainly different in -- in -- they're certainly different in geometry than the pericardial coupons and the pericardial sacs. I'm not

sure what the -- if you -- you're talking relative to the -- the actual material?

BY MR. EGAN:

Q. You -- you understand that Medtronic uses a .25 percent concentration Glutaraldehyde to treat its pericardial tissue?

A. To fix the tissue. That's a standard -- standard fixation of Glutaraldehyde, you know, solution. And there are probably thousands of solutions people use, but you always come to the same result, because you wash out the Glutaraldehyde and you always go to complete crosslinking. So I understand that that's the solution they use, yes.

Q. Okay. And you understand that the Vascutek patches use a -- a different concentration of Glutaraldehyde, correct?

A. The patches use Gluta -- I don't understand what you mean by the patches use -- you mean the material from which the patches are fabricated or fixed with a different Glutaraldehyde concentration is -- try to rephrase it and ask -- if that's your question.

Q. You're relying on the Vascutek pericardial

patches as a noninfringing alternative to porcine pericardial tissue, are you not?

MS. OBERTS: Objection to form.

THE WITNESS: No, I'm saying that they're -- that they're -- they're -- they're fashioned from -- they are or can be fashioned from the same pericardium -- the same fixed pericardium or -- or coupon, which is independent of the concentration of the Glutaraldehyde.

Glutaraldehyde concentration -- you always go to total crosslinking, total fixation. Every -- every lab in the world probably has a different PET solution that they do it with, but the end result, if you took the -- if you took the pericardium fixed in different solutions and whatever -- after it's completely washed and cleaned or whatever analysis you want, you might find some difference of thickness and so forth that's not related to the fixation.

You wouldn't -- in my opinion, you would not be able to tell precisely what solution was used to fix it. You could certainly do spectroscopic analysis and know that it was

fixed with Glutaraldehyde and not formaldehyde, but you couldn't tell anything about the -- the strength of the solution. Because it's all about the kinetics. If it's a weaker solution, you leave it in longer.

BY MR. EGAN:

Q. So it's your opinion that the concentration of Glutaraldehyde used in Medtronic's treatment processes of its porcine pericardial tissue is irrelevant to the 271(f) analysis?

MS. OBERTS: Objection to form, asked and answered.

THE WITNESS: Yeah, I'm not sure that I'd say that's irrelevant to it. I mean, it's a -- it's a -- it's a solution that they use that is effective in fixing the tissue.

When you fix -- when you fix tissue in a lab, if you've ever done that, you know, there's no black or white. You put it in until it's totally crosslinked, so it's either fixed or not fixed.

You can do it with formaldehyde. These days everyone does it with Glutaraldehyde,

but then the excess Glutaraldehyde is evaporated or washed off and so forth, and what you're left with is a completely fixed tissue which is as -- as crosslinked as you get it.

If you put it in Glutaraldehyde again, you wouldn't change it any more than it already is. You've stabilized it, you've biologically stabilized it, and the final product you get is -- is not dependent on the solution you use.

As long as the solution you use is adequate to completely crosslinkage, you have enough Glutaraldehyde to completely do the chemical reaction, then -- then that's it.

If someone fixes coupon A with -- with 20 -- 25 percent, and it all goes to completion, you wash out all the Glutaraldehyde and salts and put it back and buffer it, sterilize it, whatever, it's irrelevant. It's going to be exactly the same. And -- and it's independent of the concentration of the Glutaraldehyde solution or of other buffer salts or whatever may be -- may be present in there.

Every -- everyone has their -- it's like chicken soup, everyone has their own recipe, but it -- it's just -- and -- and often it's because one company inherits a recipe from another company and they don't want to change it for regulatory reasons and so forth.

But I would say that the -- the method of fixation, the Glutaraldehyde, specific Glutaraldehyde solution doesn't have any effect on the final coupon biological stability, which is why you're fixing it.

BY MR. EGAN:

Q. Could Medtronic change the concentration of Glutaraldehyde used in its tissue fixation process without telling the FDA?

MS. OBERTS: Objection to form.

THE WITNESS: I can't answer that because I'm not -- I'm not a regulatory person, but I -- I did talk to the people at -- I did have a phone conversation, it's in my report, with people at Medtronic, and we talked about the solution, and that was just the solution they've always used and they were happy with the solution because it worked, and -- and no one there seemed to

25 percent, in my opinion, it -- it really wouldn't -- it really wouldn't make a difference for the -- for what you achieved with the -- with the final product.

MR. EGAN: Okay. The videographer is out of tape, so let's take a break and we'll switch it.

MS. OBERTS: We can take a short break.

THE WITNESS: We are going off the record at 3:08 p.m.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: This is video number 4 in the deposition of Dr. Gary Loomis taken on April 15th, 2013. The time now is 3:23 p.m.

BY MR. EGAN:

Q. Dr. Loomis, you rely on pericardial patches such as those sold by Vascutek as examples of substantial noninfringing uses of pericardial tissue, correct?

A. Yeah, as I said that the -- I don't know if that's exactly how I worded it in my report, but I'm aware that there -- you know, that

there are patches used such as the ones sold by Vascutek that are made out of the -- made from the same pericardial coupons.

Q. Okay. And did you do any analysis to determine how often porcine pericardial patches are actually used in practice?

A. No.

Q. Okay. Do you know whether any of the porcine pericardial patches that you've identified in your rebuttal expert report are approved for use in Mexico?

A. Oh, I have no idea.

Q. Okay. I'm going to hand you what's been previously marked Plaintiff's Deposition Exhibit 34. And for the record, Plaintiff's Deposition Exhibit 34 bears Bates numbers MEDCORE 962759 to 963052.

This is another FDA submission that I think you can better capture the title of if you turn to MEDCORE 962764, several pages in. There's a cover letter dated November 9th, 2011, with a Re: line, "IDE Supplement to G100012 5-day Notice of IDE Change - Implementation of an additional option for shipping porcine tissue from Medtronic

would still be the same.

MR. EGAN: Okay.

BY MR. EGAN:

Q. So when you used the word proprietary, what do you understand proprietary to mean?

A. You know, I wasn't asked to opine on that and -- and I don't -- that's why I don't want to get into, you know, legal issues and so forth.

But I'm going to say it, I think -- I think in my mind proprietary means like something you want to guard as a trade secret because it gives you a step up on the competition, it allows you to do something that the competition can't do with their normal fixation solutions.

So you have this very special fixation solution that lets you do things that can't be done with the other solutions, so therefore you're keeping it secret. And -- and in my mind and not -- and not knowing anything about the legality of those terms, that's what I as a working scientist would say is a proprietary solution.

Q. Okay. One of the noninfringing alternatives

that you rely in your report is a pericardial patch made by Pierson Surgical, correct?

A. Yes.

Q. Okay. I'd like to hand you what we'll mark as Exhibit 507.

(Whereupon, Exhibit 507 was marked for identification.)

BY MR. EGAN:

Q. For the record, Exhibit 507 bears Bates number MEDCORE1003498.

A. Yes.

Q. Okay. And this is a product description of the No-React Porcine Pericardial Patches made by Pierson Surgical?

A. Yes.

Q. Okay. And do you see the section at the very bottom titled, "About No-React"?

A. Yes.

Q. Okay. And the second paragraph in that section reads, "The No-React treatment is a Heparin-based proprietary detoxification and biomodification of Glutaraldehyde-treated tissue that further stabilizes tissue crosslinking and prevents the release of aldehydes."

A. Uh-huh.
Q. Do you see that?
A. Yes.
Q. So do you agree that the Pierson Surgical porcine pericardial patch on which you're relying is treated with a proprietary Glutaraldehyde solution?
MS. OBERTS: Objection to form.
THE WITNESS: The -- the Glutaraldehyde -- the solution that they have is a -- is a -- it's -- it's not -- if you read it, the treatment is not a fixation solution, it's a heparin-based proprietary detoxification and biomodification system.
So it's a solution, they've gotten a trademark for it, they don't want to tell you the exact concentration of heparin or exactly what kind of heparin, which is an anticoagulant, they used and so forth.
So they're essentially -- have a solution here that's essentially made with a -- with a drug, with heparin, with a biological agent. And it's like most pharmaceutical companies don't tell you exactly, except what they're required by the FD -- with the FDA as to how

they put their solution together and so forth.

So as I say, this is -- this is because -- this is about the -- the solution that they -- that they put it into when they -- when they -- when they sell it. This is their No-React solution that they put it into after starting -- after starting with a fixed -- a fixed pericardium, and that's what I -- a fixed tissue.

That's what I'm getting from this, that their -- their term proprietary is that they've got this detoxification and biomodification treated tissue, that further stabilizes it.

So they've already started with stabilized tissue and then they've done it with another solution that they've added to it which they claim is called No-React and it further stabilizes it and it has a lot more in it than just Glutaraldehyde and -- and buffer salts.

The solution with Medtronic for fixation, all they have are -- are -- are normal buffer salts and Glutaraldehyde and water. This

thing that has -- is a heparin-based system, so this -- and there are so many different forms of heparin or heparin sulphate that one could use.

And so I think that's -- that's what's proprietary about this. It's very -- it's very different because it has this added component that does more than just fix the tissue, because it's a known -- it's a known treatment for, you know, non-throm -- non-thrombotic properties to prevent thrombosis.

So I don't think this relates -- I don't think this -- what they're calling a proprietary solution is the kind of solution that's anything like what -- you know, what Dr. Buller attests that Medtronic solution is proprietary solution. It's a completely -- it's a completely different thing.

MR. EGAN: Okay.

BY MR. EGAN:

Q. You haven't seen any evidence of Medtronic treating its pericardial tissue with a solution that includes heparin, have you?

A. Not that I know of.

the record at 4:40 p.m.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: This is video number 5 in the deposition of Dr. Gary Loomis taken on April 15th, 2013. The time now is 4:56 p.m.

BY MR. EGAN:

Q. Dr. Loomis, could you turn to page 9 of Exhibit 502, which is your rebuttal report.

A. Yes. Page 9.

Q. Okay? Are you there?

A. Yes.

Q. Okay. And the second to last paragraph reads, "I have also been told to assume that under 271(f)(2) it is not --

A. Where are we? Where are we at? Page 6?

Q. No, page 9.

A. Oh, page 9.

Q. The second to last paragraph.

A. It was upside down.

MS. OBERTS: I think the pages are out of order.

THE WITNESS: The pages are out of order. There we go. That's what it was.

That's that two-sided thing.

MR. EGAN: That's not too bad for six hours and only turning one page over.

BY MR. EGAN:

Q. So are you on page 9?

A. Yes.

Q. Okay. And do you see the second to last paragraph that reads --

A. Yes.

Q. -- "I have also been told to assume that under 271(f)(2) it is not necessary that the component actually be used by Medtronic or by anyone in any other fashion, but only that the component be suitable for substantial noninfringing use." Do you see that?

A. Yes, I do see that.

Q. Okay. And did you follow your counsel's instruction and make this assumption in your report?

A. I made the assumption in the report that it would be suitable for noninfringing use, yeah.

Q. Okay. And your opinion is premised on this assumption, correct?

A. My overall opinion is premised on that -- on

that assumption.

Q. Okay. If I could turn your attention to the paragraph just above that, it reads, "I understand that under 271(f)(1) a substantial portion of the components must be supplied, and I have been told to assume that more than one component must be supplied." Do you see that?

A. Yes.

Q. Okay. And did you follow your counsel's instruction and make this assumption in your report?

A. Yes.

Q. Okay. And your opinion is premised on this assumption?

A. Yes.

Q. Okay. Could you turn to page 37 of your rebuttal report.

A. (Complies.)

Q. Okay. And just above section B that's titled, "An 18 French Arterial Introducer," do you see the paragraph starting, "I have been asked"?

A. Yeah. Yes.

Q. Okay. You write, "I have been asked to